

COGR

an organization of research institutions

COUNCIL ON GOVERNMENTAL RELATIONS

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Subject: CMS Conflict of Interest Procedures

Thank you for taking the time to speak with us in April regarding our questions pertaining to the CMS Conflict of Interest requirements and our subsequent follow-up emails up to this point. Since our discussion, we've taken the time to gather more input from our members we believe you may find helpful as we work together to find a more workable and less burdensome process to manage, reduce or eliminate conflict of interest pertaining to financial assistance awards and contracts for research institutions.

In May, COGR met with the OMB to present a status update on areas of concern since implementation of the Uniform Guidance. Among them, we discussed the lack of harmonization among agency requirements as it pertains to conflict of interest and the lack of clarity regarding the direction §200.112 was meant to take, i.e., personal conflicts of interest/scientific integrity vs organizational conflicts of interest/procurement. I've attached our letter to the OMB that may prove beneficial when we schedule a future teleconference to discuss these matters. In the meantime, the input we've gathered from our members concerning CMS' requirements are as follows:

- **Assessment at Proposal:** The requirement of disclosure of organizational and personal conflicts of interests at the time of application is overly burdensome considering the low probability of funding.
- **Financial Interests/Relationships:** If an institution is already required to list and assess potential organizational conflicts of interests as defined by the regulations, what is the purpose of this additional section on the institution's financial interests or relationships? The federal regulatory basis for this requirement is unclear.

- **Confusing sub-contractor directions:** It is unclear for sub-contractors which part of the J.X form is required at the time of proposals to pass along to the prime applicants as D.1 indicates all information on the J.X form but D.2 states the Prime Contractor should obtain the COI disclosures [personal?] at the time of award.
- **Scope of personal disclosures:** The broad range of individuals from which disclosures must be collected goes beyond the scope of those who could have a meaningful impact on the project (e.g., Governing Body Members, Board of Directors, Trustees, Principals of the Organization as defined by FAR 52.203-14).
- **Definitions of personal reportable interests:** The far-reaching definitions of reportable Significant Financial Interest, many of which will have no bearing on the program or contract and which go beyond that required by other federal agencies, such as: healthcare sector mutual funds and healthcare related real estate, loans over \$10K from an individual, such as a friend or business associate employed by a healthcare entity, or who has a business association with a healthcare entity, all healthcare related positions both paid and unpaid held in the past 2 years (e.g. director, employee, trustee), including at educational institutions (e.g. teaching hospital), all non-employer healthcare, travel-related reimbursements totaling more than \$250 and any gifts from healthcare related companies with a fair market value totaling more than \$250 (for discloser, spouse/domestic partner, and/or and dependent).
- **Audit Requirements:** The mandatory independent/external audit requirements for mitigation if potential conflicts are identified on form J.X, are unnecessary, highly burdensome, and without provisions for covering cost.
- **Oversight Program:** The COI Oversight Program requirement for contracts >\$5M (section H of a CMSRFP) requiring items above and beyond any existing program requirements including Display of Fraud Hotline Posters in accordance with FAR 52.203-14, internal and external audit, preventing COIs and obtaining signed non-disclosure agreements to prohibit disclosure of non-public information accessed through the contract.

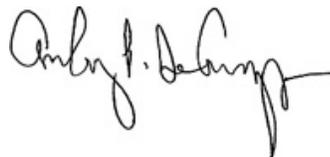
Our member institutions submit many federal proposal applications on a routine basis. The amount of information required to be collected, reviewed and subsequently disclosed, if applicable, at the time of proposal for financial assistance awards and contracts by the Institution itself and Regents, Trustees, Board members, etc., seems excessive and unnecessary. In particular, given that many institutions are large and complex organizations of higher education or health care at which Regents, Trustees, Board members, etc., are not engaged in the operational oversight or administration of research or other award activities, let alone involved in specific research project design, conduct, or reporting of research results, collecting the personal financial interest of these individuals appears to be unrelated to the research project or contract itself. Finally, the success rates of funding overall equates to approximately 10% of proposals submitted; even if success rates were higher, the amount of information required such as the

development of a mitigation plan to be submitted at time of application is impractical and far more burdensome than any agency requirements imposed to date.

Scientific conflict of interest policies such as those under the Public Health Service (PHS) or the National Science Foundation (NSF) have been in place for several years and institutions have infrastructures to manage, reduce or eliminate conflicts of interest prior to the expenditure of award funds. Although significant financial interest disclosures are required at the proposal stage, they are only required from “Investigators”, defined as a principal investigator, co-principal investigators/co-project directors, and any other person at the institution who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by these agencies. Additionally, most other sponsor policies specifically exclude certain types of financial interests and relationships from disclosure by investigators that CMS does not exclude (e.g., investment vehicles such as mutual funds or retirement accounts when the investigator does not directly control the investment decisions made in these vehicles, compensation and reimbursed travel provided by the institution at which the investigator is employed, etc.). These exclusions to disclosure requirements are allowed by other sponsors because of the limited potential of these types of interests and relationships to present actual conflict of interest concerns. Disclosure of these types of interests and relationships is extensive, and onerous for investigators, and unnecessary.

We appreciate the opportunity to work with you. We understand the goal of CMS to provide a fair and level playing field at the time of award as well as fair and unbiased recommendations, judgment and and/or advice provided to the government during any contract performance. We believe research institutions can meet those goals while addressing the concerns above. Ideally, we hope to achieve harmonization with these policies in the coming months with our federal sponsors. Please let me know if you have any further questions. We look forward to discussing this at your earliest convenience. I can be reached at (202) 289-6655 or jbendall@cogr.edu.

Sincerely,

A handwritten signature in black ink, appearing to read "Anthony DeCrappeo". The signature is fluid and cursive, with a long horizontal stroke at the end.

Anthony DeCrappeo

President